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09/938,667	08/27/2001	Jens Petersen	60117.000006	2505

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EXAMINER	
FUBARA, BLESSING M	
ART UNIT	PAPER NUMBER
1618	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/24/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/938,667	PETERSEN, JENS	
	Examiner	Art Unit	
	Blessing M. Fubara	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9-17,29-32,34-38,52-55,57,62,63,67-69 and 78-84* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-17,29-32,34-38,52-55,57,62,63,67-69 and 78-84* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/01/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt of amendment and communication filed 10/20/06 in response to the Election/Restriction requirement. Applicant added new claims 78-84; canceled claims 71-77 that were directed to treating anal incontinence. Claims 9-17, 29-32, 34-38, 52-55, 57, 62, 63, 67-69 and 78-84 are thus pending in the application.

Election/Restrictions

1. Applicant's election of Group I, drawn to method of treating urinary incontinence, in the reply filed on 10/20/06 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Furthermore, applicant has canceled claims 71-77 drawn to treating anal incontinence and reserving the right to file one or more divisional applications directed to the non-elected method of treating anal incontinence.

2. Previous rejections that are not reiterated herein are withdrawn.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

5. Claims 14, 54, 57, 62, 63, 79 and 81-84 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is new matter rejection.

Original claims 1, 7, 8 and 14 recite pyrogen-free water and saline solution and the original specification at paragraphs [0001], [0012], [0016], [0020], [0027], [0028] and [0030] disclose pyrogen-free water and saline solution.

The recitation, therefore, of generic water and aqueous solution in the claims introduces new matter into the claims because the use of water that is not free of pyrogens and the use of aqueous solution that is not a saline solution is not supported by the as filed specification as noted above.

The above rejection can be overcome by reciting pyrogen free water and saline solution in place instead of the now recited and unsupported water and aqueous solution.

6. Claims 10-17, 29-38, 52-55, 57, 63, 63, 67-69, 78 and 79 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for urethra, rectum, colon and ureter as conduits, does not reasonably provide enablement for all canals/channels that are conduits as is recited in original claim 18. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. This is scope of enablement.

Enablement is considered in view of the Wands factors (MPEP 2164.01(a)). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (*Wands*, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (*Wands*, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient number of the factors are discussed below for a *prima facie* case.

1. The Nature of the Invention:

The invention in the designated claims is drawn to injecting acrylamide hydrogel into conduit.

2. State of the prior art:

Conduit can mean a host of channels or canals through which fluids can flow. For example, according to the online Moby Thesaurus, conduit can mean any one of **Eustachian tube, Fallopian tube, channel, duct, fistula, gash, intestines, neck, ostium, oviduct, thoracic duct, throat, trench, ureter, urethra, vagina, vas, vessel and wrinkle** (see paragraph 6 of this

communication under claim 54). Further, applicant in the interview conducted 2/23/06 stated that RU reference 2148957 injects acrylamide hydrogel into the ostium of the ureter, which supports the practice that acrylamide hydrogels can be injected into conduits other than urethra, for example.

Furthermore, it is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. *In re Fisher,* 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific guidance is required to enable the artisan to practice the full scope of the claimed invention.

In the instant case, the scope of the conduit spans all canals that qualify as conduits as listed in paragraph 6 of this communication under claim 54.

3. The amount or direction or guidance presented:

Guidance is given for urethra, rectum, colon and ureter and not for other conduits.

Therefore, in view of the lack of guidance, working examples, breadth of the claims and state of the art at the time the claimed invention was made, it would have required undue experimentation to use the invention as claimed. It is noted that the specification must teach those of skill in the art how to make and how to use the invention as broadly claimed. In re Goodman, 29 USPQ2d at 2013 (Fed. Cir. 1994), citing In re Vaeck, 20 USPQ2d at 1445 (Fed. Cir. 1991). The courts have stated that reasonable correlation must exist between scope of exclusive right to patent application and scope of enablement set forth in patent application. 27 USPQ2d 1662 *Ex parte Maizel.* Scope of Enablement is considered in view of the Wands factors (MPEP 2164.01 (a)).

The above rejection may overcome by specifically recited the conduits disclosed in the original specification

7. Claims 9-17, 29-32, 34-38, 52-55, 57, 62, 63, 67-69 and 78-84 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The hydrogel in the generic claims is in amount of about 0.5% to 25% of the total weight of the hydrogel and it is confusing how the "hydrogel" is of a certain amount of the "hydrogel."

The as filed specification in the abstract and in at least paragraphs [0001], [0012], [0013], [0016], [0035] and [0037] and original claims 1 and 9 state that 0.5 to 25% of the hydrogel is polyacrylamide.

The above rejection may be overcome by clarifying the what "0.5% to 25%" in the claims represent and reciting same in the claims so long as such a recitation in supported by the original specification without the introduction of new matter. See applicant's specification at paragraphs [0001], [0012], [0013], [0016], [0035] and [0037] and original claims 1 and 9 (published application).

The Claims:

Claim 9 is drawn to method of treating urinary incontinence, the method comprises administering endoprosthesis that includes "hydrogel in an amount of 0.5 to 5% by weight based on the total weight of the hydrogel, of a polymer prepared by a method comprising combining acrylamide and methylene bis-acrylamide: wherein the hydrogel includes less than 50 ppm

monomeric units, has a complex viscosities of about 2-50 Pas and has an elastic modulus of about 1-200 Pa."

No specific site of administration is recited such that administration of acrylamide hydrogel would inherently treat urinary incontinence. "For urethral bulking" is an intended use of the hydrogel and/or the properties/characteristics/effect of the administered acrylamide hydrogel. "Prepared by a method ... bis-acrylamide," is the process of preparing the acrylamide hydrogel. "Less than 50 ppm monomeric units" in the hydrogel represent residual amounts of the starting acrylamide monomer and the cross-linker methylene bis-acrylamide. The viscosity and the elastic modulus are inherent properties of the hydrogel.

Claim 54 is similar to claim 9 except that in claim 54, the hydrogel is injected directly into a conduit. A conduit is a channel for conveying fluids or in this case, hydrogel. "For urethral bulking" is an intended use of the acrylamide hydrogel. "Fewer than 50 ppm monomeric units" in the hydrogel represent residual amounts of the starting acrylamide monomer and the cross-linker methylene bis-acrylamide. The viscosity and the elastic modulus are inherent properties of the hydrogel.

From Moby Thesaurus II by Grady Ward, 1.0 [Moby-thesaurus] on line search returned the below synonyms:

104 Moby Thesaurus words for "canal":

Eustachian tube, Fallopian tube, aqueduct, arroyo, bed, bottleneck, canalization, canalize, carve, chamfer, channel, chisel, conduit, corrugate, course, crack, creek bed, crimp, culvert, cut, dado, defile, dike, ditch, donga, dry bed, duct, emunctory, engrave, entrenchment, fistula, flume, flute, fosse, furrow, gash, gofer, gouge, groove, gulch, gully, gullyhole, gutter, ha-ha, headrace, incise, intestines, irrigation ditch, isthmus, kennel,

meatus, moat, narrow, narrows, neck, nullah, ostium, oviduct, pass, pleat, plow, pore, rabbet, race, rifle, river bed, riverway, runnel, rut, salpinx, score, scratch, slit, sluice, spillbox, spillway, strait, streak, stream bed, streamway, striate, sunk fence, swash, swash channel, tailrace, thoracic duct, throat, trench, trough, ureter, urethra, vagina, vas, vessel, wadi, water carrier, water channel, water furrow, water gap, water gate, watercourse, waterway, waterworks, wrinkle.

Thus ostium, urethra, Eustachian tube, Fallopian tube and canal are synonymous with conduit.

Claim 78 is similar to claim 9 except that the intended use of the acrylamide hydrogel in claim 78 is to "increase resistance in a conduit."

Claim 79 is similar to claim 54 except that the intended use of the acrylamide hydrogel in claim 78 is to "increase resistance in a conduit."

Claim 80 is similar to claim 9 except that the intended use of the acrylamide hydrogel is for bulking.

Claim 81 directly injects the acrylamide hydrogel as a bulking agent; no site of injection is recited.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 9-15, 29-31, 34-36, 52-54, 62, 63, 67-69 and 78-84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pavlyk (US 5,798,096) in view of RU 2148957 and further in view of applicants admission (interview of 2/23/06 and remarks filed 2/27/06).

Generic claims 9, 54 and 78-81 are analyzed above under "**The Claims**:" It is noted in the analysis for claim 9 that the method of treating urinary incontinence comprises and administration step that is not specific to any administration site such administration of acrylamide hydrogel by the prior art would inherently treat urinary incontinence; that the process of making the hydrogel is a product by process and the prior art only has to disclose the structure of the product to meet the process for making the hydrogel; that the complex viscosity and the modulus of elasticity are properties inherent to the hydrogel. Claims 54 and 79 inject the hydrogel into a conduit, which a canal or channel or tube. Claims 78, 80 and 81 administer the endoprosthesis and increasing the resistance in a conduit and bulking are intended uses of the hydrogel. The other aspects of the properties of the hydrogel as described for claim 9 is the same for the claims 54, 78-81. Pavlyk in view of RU 2148957 and further in view of applicant's admission (interview of 2/23/06 and remarks filed 2/27/06).

Pavlyk discloses cross-linked polyacrylamide hydrogel (claims 52 and 53) produced from acrylamide and methylene bis-acrylamide monomers and apyrogenic or pyrogen free water (abstract; Table 1) meeting the limitations of the acrylamide hydrogels and pyrogen free water of the claims; the hydrogel is used as endoprosthesis by way of sterile injections into tissues by way of canals of the corporum cavernosum (column 1, lines 5-10; column 10, lines 37-56). Pavlyk discloses that the hydrogel provides bulking (column 3, lines 17-18); the hydrogel of Pavlyk has

low viscosity (column 2, lines 58-67) and the Pavlyk hydrogel would inherently have the viscosity properties recited. The amount of the acrylamide in the hydrogel ranges from 3.5 to 9.0% touching pints along the claimed acrylamide range of 0.5 to 25% as in the generic claims 9, 54 and 78-81. The hydrogel of Pavlyk would inherently exhibit the intended use of the claimed hydrogel and would have the claimed properties since a product and its properties cannot be separated and thus meets claims 13, 35, 36, 67-69. The 3.5% acrylamide of Pavlyk is less than 15%, 10%, 7.5%, 5% (claims 11, 29-31) and 3.5% is at least 1%, 1.6% (claims 12, 34). The amount of water or aqueous solution in Pavlyk ranges from 88% to 96% (see Table 1) meeting the water limitation of claims 14, 62 and Pavlyk's use of pyrogen free water meets claims 63. Since the reaction between the acrylamide monomer and the methylene bis-acrylamide monomer cross-linking agent goes to completion, since the Pavlyk reference does not disclose the presence of residual monomeric units in the acrylamide hydrogel, and since the residual monomer in the product is expected to be very minimal if any, Pavlyk renders less than 50 ppm monomeric unit obvious.

While Pavlyk discloses injecting the hydrogel into caverns that may meet canals or conduits or channels, and if the cavern does not specifically read on channels or tubes, it is known according to the RU reference 2,148,957 and as admitted by applicant that the acrylamide of Pavlyk is known and used for injection into the ostium of the ureter in the treatment of urinary incontinence (see paragraph of remarks filed 10/27/06). Therefore, it would have been obvious to one of ordinary skill in the art to inject hydrogel into the caverns that would exhibit act as a bulking agent. One having ordinary skill in the art would have been motivated to inject the

acrylamide hydrogel into the ostium of the ureter with the expectation that the hydrogel would act as a bulking material and lead to the treatment of urinary incontinence.

10. Claims 9-17, 29-32, 34-38, 52-55, 57, 62, 63, 67-69 and 78-84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vogel et al. (US 6,335,028) in view of RU 2148957 and further in view of applicants admission (interview of 2/23/06 and remarks filed 2/27/06).

Vogel discloses method of treating urinary incontinence by administering, by injection into esophageal wall or via the urethra and into the wall of the bladder sphincter and urethral wall, acrylamide based hydrogel produced with about 25 to about 98% methacrylamide and about 2-about 50% methylene bis-acrylamide and containing autologous cells (abstract; column 4, lines 31, 32, 51-67; column 6, lines 1-16; column 10, lines 40-44; Examples 1 and 2); sterile and pyrogen free injectable solutions are employed for the storage of the hydrogel product (column 6, lines 58-60). Since the Vogel reference does not disclose the presence of residual monomeric units in the acrylamide hydrogel, and since the residual monomer in the product is expected to be very minimal if any, Vogel renders less than 50 ppm monomeric unit obvious.

Vogel discloses injectable acrylamide based hydrogel, and being injectable, it would have inherent viscosity that is characteristic of injectable hydrogels such as the claimed viscosities. The hydrogel contains cells (column 4, line 57) or other active agents (column 10, lines 54-67). The viscosity and modulus of elasticity are properties of the hydrogel. The amount of the polyacrylamide would approximate the amount recited since the starting amount of the acrylamide is at about 25% and the expected amount of the end product would be less than the starting 25%. Vogel does not state that the hydrogel is a prosthesis. But it is known that acrylamide based hydrogels are used as endoprosthesis for administration into the ostium of the

ureter for treating urinary incontinence according to RU 2148957 and applicant's admission (interview of 2/23/06 and remarks filed 2/27/06). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to inject the cross-linked polyacrylamide based hydrogel of Vogel through the urethra to treat urinary incontinence. One having ordinary skill in the art would have been motivated to administer the hydrogel of Vogel as a prosthetic device with the expectation bulking the urethra to treat urinary incontinence.

Suggestion:

It is suggested to applicant, as was suggested previously and as stated on page 8 of applicant's remarks of 10/20/06, that the hydrogel be injected into urethra at 0.5 cm distally from the neck of the bladder to overcome the art, explanation of why that position provides unusual and unexpected result may be necessary. Please not that Vogel injects hydrogel of the type claimed into the urethra.

Response to remarks at the 4th full paragraph of page 8 of the remarks of 10/20/06:

The material used in the bulking is well known according to RU 2148957 and further according to applicant's admitted prior art (interview of 2/23/06 and remarks filed 2/27/06); and both Pavlyk (US 5,798,096) and Vogel et al. (US 6,335,028) disclose cross-linked polyacrylamide hydrogels that are used as bulking agents. The claims lacked written description for injecting the hydrogel into the neck of the bladder. "Depots 0.5 cm distally from the neck of the bladder" is envisioned at the time of filing (paragraph [0042] of applicant's published application). While other references can be used to support enablement, they are not usually useful for showing written description.

Other Matters:

The claims have several periods within each claim. A claim must begin with a capital letter and end with a period. Correction is respectfully requested.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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